

# Notice of Allowability

Application No.

10/035,320

Examiner

Frederick F. Krass

Applicant(s)

BARABOLAK ET AL.

Art Unit

1614

## -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment dated 8-20-05.
2. ☒ The allowed claim(s) is/are 6-8 and 10-14.
3. ☐ The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

### Attachment(s)

- |   |   |
|---|---|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                                 |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date <u>8-23-05</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment   |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material          | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance                        |
|   | 9. <input type="checkbox"/> Other _____.  |

**Examiner's Amendment**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Thomas Basso on August 23, 2005.

The following changes have been made:

1) Claim 12, first line, immediately before "each" there has been inserted --- said gum comprises pieces, and ---

2) As the first line of the specification there has been inserted:

--- This application is a continuation of U.S.S.N. 09/453,383, filed on 12/02/99, and now USP 6,436,369, and claims the benefit of US Provisional Applications 60/112,641, filed 12/17/98, and 60/118,330, filed 02/03/99, respectively. ---

3) At page 8 of the specification the following changes have been made:

- i) "NutraFlora" has been changed to --- NUTRAFLORA ---
- ii) "Sun Fiber" has been changed to --- SUN FIBER ---
- iii) "Fibersol" has been changed to --- FIBERSOL ---

### **Reasons for Allowance**

The following is an examiner's statement of reasons for allowance:

The claims are allowable for the reasons provided in the prior Office Action (Advisory Action).

Furthermore, the obviousness-type double patenting rejection over USP 6,436,369 is withdrawn since, upon review of the case, the examiner notes that a terminal disclaimer was in fact filed over the patent on 4/22/00 (at a time when prosecution was being handled by a previous examiner).

USP 6,592,912 is cited as further demonstrating the state of the art; it has a common inventor and assignee with the instant application and discloses chewing gums for the controlled release of antimicrobials. Useful antimicrobials include triclosan, cetylpyridinium chloride, hexylresorcinol, and chlorhexidine digluconate, with the latter being preferred. (Col. 2, lines 61-67). The reference provides no direction, however, for combining triclosan and cetylpyridinium chloride together, let alone emulsifying the mixture. Note that all preferred embodiments, including the working examples, disclose the use of chlorhexidine digluconate alone. Furthermore, the patent clearly indicates that triclosan is very poorly water soluble, while cetylpyridinium chloride is fully sixty six times more soluble: see col. 3, lines 1-6. Based on this specific disclosure, one would hardly be motivated to add triclosan to an aqueous composition containing cetylpyridinium chloride. Accordingly, no prima facie case of obviousness exists; indeed, the prior art would actually tend to lead one away from the specific combination of ingredients recited instantly.

Moreover, the prior is silent regarding increased antiplaque activity. Thus, the prior art could in no way have predicted that an emulsified combination of triclosan and cetylpyridinium chloride, when used in the coating of a chewing gum, would unexpectedly provide increased antiplaque activity (thus permitting the use of lower amounts of each, further providing the corollary unexpected benefit of decreased unpleasant taste and/or sensation), as factually demonstrated by the experimental results provided at pages 12 and 13 of the instant specification.

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Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

### **Correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick F. Krass whose telephone number is 571-272-0580. The examiner's schedule is 9:30AM – 6:00PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass  
Primary Examiner  
Art Unit 1614

